



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	4570.20
True Name	Bovine Rotavirus -Coronavirus Vaccine, Killed Virus, Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Scour Bos 9 - Elanco Canada Limited - Elanco US Inc. Scour Bos 9 - Elanco US Inc.
Date of Compilation Summary	May 01, 2020

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Clostridium Perfringens Type C (CPTC)
<b>Study Purpose</b>	To demonstrate passive immunity against CPTC
<b>Product Administration</b>	Intramuscular to pregnant heifers
<b>Study Animals</b>	Calves
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	November 19, 1999

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Coronavirus
<b>Study Purpose</b>	To demonstrate passive immunity against Bovine Coronavirus in calves
<b>Product Administration</b>	Intramuscular to pregnant heifers
<b>Study Animals</b>	Calves
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	November 18, 1999

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Escherichia Coli
<b>Study Purpose</b>	To demonstrate effectiveness against Escherichia Coli in calves
<b>Product Administration</b>	Pregnant cattle
<b>Study Animals</b>	Calves
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	April 21, 1999

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Rotavirus
<b>Study Purpose</b>	To demonstrate passive immunity against Bovine Rotavirus in calves
<b>Product Administration</b>	Intramuscular to pregnant cattle
<b>Study Animals</b>	Cattle
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	November 18, 1999

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	To demonstrate safety under typical field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	NA
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	November 22, 1999